IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

DAVID ZINK, et al.,)
Plaintiffs,	Case No. 12-4209-CV-C-BP
v. GEORGE A. LOMBARDI, et ai., Defendants.	THIS IS A CAPITAL CASE Execution scheduled for February 26, 2014

PLAINTIFF TAYLOR'S REPLY IN FURTHER SUPPORT OF MOTION FOR STAY OF EXECUTION PENDING RULING ON CERTIORARI

Taylor merits a stay for the brief period it will take the Supreme Court to decide whether to take his case. There is a reasonable probability the Court will grant certiorari, a significant possibility the Court will reverse the Eighth Circuit, and the irreparable harm Taylor faces absent a stay outweighs the state's desire to execute him before the Court rules. A stay is warranted and reasonable.

I. Barefoot Sets Forth the Standard Here and Taylor Meets It

The Supreme Court has expressly stated the standard for granting "[s]tays of execution . . . pending the filing and consideration of a petition for a writ of certiorari." *Barefoot v. Estelle*, 463 U.S. 880, 895 (1983). "It is well-established that there must be a reasonable probability that four members of the Court would consider the underlying issue sufficiently meritorious for the grant of certiorari or the notation of probable jurisdiction; there must be a significant possibility of reversal of the lower court's decision; and there must be a likelihood that irreparable harm will result if that decision is not stayed." *Id.* (internal punctuation and citations omitted). That is the standard here; defendants ignore it.

Rather than acknowledge *Barefoot* or the fact that it sets the standard for Taylor's motion for a stay pending certiorari, defendants say the Court "should" apply the standard for a stay alluded to in *Hill v. McDonough*, 547 U.S. 573 (2006). (Docket 349 at 1) Yet *Hill* does not address the situation here: a litigant seeking a stay for the short time it will take the Supreme Court to grant or deny certiorari. The *Hill* Court addressed a different question: whether "[f]iling an action that can proceed under § 1983 . . . entitle[s] the complainant to an order staying an execution as a matter of course." *Id.* at 583-584. The Court said no because the simple act of challenging an execution should not, by itself, override the "important interest in the timely enforcement of a sentence." *Id.* at 584. The Court ruled Hill had the right to challenge the method of his proposed execution in a § 1983 action, however, and because the lower courts had held to the contrary, the Supreme Court remanded the matter for litigation of the § 1983 suit and any motion for a stay of execution pending the ultimate resolution of that suit. *Id.*

That is not the situation here. Taylor does not request a stay of execution for however long it might take to finally adjudicate plaintiffs' § 1983 suit. He instead seeks a stay for the brief time – days or weeks, not months or years, *see* Sup Ct. R. 15.5 – it will take the Supreme Court to grant or deny the already-filed certiorari petition. *Barefoot* sets the standard for the request here, and *Hill* did not even address – let alone purport to overrule – that standard. Taylor meets it.

A. Reasonable Probability of Certiorari Being Granted

Defendants do not dispute that, "[w]hen a CFR [call for response] is issued, it is a strong sign that the Court is interested in hearing argument in a case." D. Thompson et al., *An Empirical Analysis of Supreme Court Certiorari Petition*

Procedures, 16 Geo. Mason L. Rev. 237, 250 (2009).

That is the case here. On February 3, 2014, the Court issued a CFR: it called for a "[f]urther [r]esponse" from defendants, due March 5, 2014, as to whether certiorari should be granted. *See* Sup. Ct. Docket No. 13-8435.

Defendants suggest the CFR is not really a CFR because they "owe" a response "under Rule 15.1." (Docket 349 at 9) They already filed that "owed" response, however, on January 28, 2014. They titled it "Suggestions in Opposition to Motion for Stay of Execution and to Petition for Writ of Certiorari" and devoted an argument point to why the "Court should not grant the petition for a writ of certiorari." (Exhibit A) (emphasis added) Indeed, it was docketed as "Brief of respondent in opposition and response to application (13A784) for a stay of execution." Sup. Ct. Docket No. 13-8435 (emphasis added). After defendants filed that response, the Court requested another. No such additional response was "owed" and the Court's calling for one "is a strong sign that the Court is interested in hearing argument in a case." Thompson, *supra*, at 250.

And that is not surprising. As defendants also do not dispute, "[s]uits challenging lethal injection on Eighth Amendment grounds are legion in state and federal courts alike" and the question on certiorari here – as to the proper pleading standard for such suits – is an "oft-posed question of national importance." (Docket 343 at 4, 5) This adds to the reasonable probability certiorari will be granted, as does the fact that the Eighth Circuit's ruling "conflicts with relevant decisions of th[e Supreme] Court" and of "another United States court of appeals on the same important matter." Sup Ct. R. 10(a), (c).

As to the circuits Taylor identifies as being in conflict with the Eighth,

defendants say "there is no real conflict" because those circuits do "not address" the question here. (Docket 349 at 5) That is wrong.

"For [a plaintiff] to establish his Eighth Amendment claim" under *Baze v*.

*Rees, 553 U.S. 35 (2008), the Ninth Circuit has held, "he is required to show a risk that is 'sure or very likely to cause . . . needless suffering,' and give[s] rise to 'sufficiently imminent dangers." *Cook v. Brewer, 649 F.3d 915, 917 (9th Cir. 2011) (ellipsis in *Cook*). If the Ninth Circuit believed such a plaintiff also had to identify, as the Eighth Circuit held here, "a feasible and more humane alternative method of execution," *In re Lombardi*, ____ F.3d ____, 2014 WL 288937 at *7 (8th Cir. 2014) (en banc), it would have said so.

"In the lethal injection context" under *Baze*, the Eleventh Circuit has likewise held, the Eighth Amendment "standard requires an inmate to show an objectively intolerable risk of harm that prevents prison officials from pleading that they were subjectively blameless for purposes of the Eighth Amendment.

[T]he risk must be sure or very likely to cause . . . needless suffering." *DeYoung v. Owens*, 646 F.3d 1319, 1325 (11th Cir. 2011) (internal punctuation and citations omitted). As with the Ninth Circuit, the Eleventh Circuit has not required such a plaintiff to identify "a feasible and more humane alternative method of execution."

These rulings conflict with those of the Fifth, Sixth and Eighth Circuits. *See Whitaker v. Livingston*, 732 F.3d 465, 468 (5th Cir. 2013) ("Under *Baze*," a "plaintiff can therefore succeed on an Eighth Amendment claim in this context only if he can establish both that the state's protocol creates a demonstrated risk of severe pain and that that risk is substantial when compared to the known and available alternatives."); *Raby v. Livingston*, 600 F.3d 552, 560-561 (5th Cir.

2010) (same); *Cooey v. Strickland*, 589 F.3d 210, 220 (6th Cir. 2009) ("*Baze* requires" that "an inmate cannot question a state's execution protocol without providing 'feasible, readily implemented' alternatives.").

Even if the conflict above is not express, it is real: practically speaking, a plaintiff alleging an unconstitutional method of execution in California is held to a different standard than such a plaintiff in Texas. This kind of disparate treatment of litigants rasing the same claim is the kind of discord the Supreme Court often resolves. *See Jones v. Bock*, 549 U.S. 199, 203 (2007) ("We granted certiorari to resolve the conflict" as to the exhaustion requirements of Prison Litigation Reform Act.); *Zedner v. United States*, 547 U.S. 489, 497 (2006) ("We granted certiorari to resolve the disagreement among the Courts of Appeals on the standard for analyzing whether a defendant has made an effective waiver of rights under the [Speedy Trial] Act."); *Ornelas v. United States*, 517 U.S. 690, 695 (1996) ("We granted certiorari to resolve the conflict among the Circuits over the applicable standard of appellate review" as to probable-cause findings.).

In sum, the Supreme Court has demonstrated its interest in this case by calling for a further response regarding an important and oft-posed question that has, at the very least, confused the circuits and led to disparate pleading standards for the same constitutional claim. Though the certiorari petition is now before the Supreme Court, this Court may enter a stay and, indeed, the Supreme Court has made clear this Court should do so where warranted. *See* Sup Ct. R. 23.3 (applicant should not seek stay from Supreme Court unless "the relief sought is not available from any other court"). As discussed in Taylor's motion and herein, a stay pending certiorari is warranted and reasonable in this case.

B. Significant Possibility of Reversal

At issue here is the Eighth Circuit's 7-3 ruling that plaintiffs' Eighth Amendment challenge to Missouri's execution protocol was improperly pleaded because plaintiffs did not identify "a feasible and more humane alternative method of execution." *Lombardi*, F.3d , 2014 WL 288937 at *7.

That is not the law. As the Supreme Court unanimously noted in 2007, "just last Term, in *Hill v. McDonough*, 547 U.S. 573, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006), we unanimously rejected a proposal that § 1983 suits challenging a method of execution must identify an acceptable alternative." *Jones v. Bock*, 549 U.S. 199, 213 (2007). This is because "[s]pecific pleading requirements are mandated by the Federal Rules of Civil Procedure, and not, as a general rule, through case-by-case determinations of the federal courts." *Id.* (quoting *Hill*, 547 U.S. at 582; citing *Swierkiewicz v. Sorema N. A.*, 534 U.S. 506, 512-514 (2002)).

Defendants say "[t]here is no real conflict between *In re Lombardi* and the decisions in *Hill*, *Jones* and *Baze*." (Docket 349 at 8) That assertion is rather incredible, and it is wrong.

As quoted in relevant part above, *Hill* and *Jones* squarely and unanimously reject the Eighth Circuit's notion that Eighth Amendment plaintiffs must identify "a feasible and more humane alternative method of execution." Defendants try to get around *Hill* and *Jones* by saying those decisions rejected "the need to name an alternative feasible method of execution *as a heightened pleading requirement,*" but "not as a *core element of an Eighth Amendment claim*, as the Court later found it to be in *Baze*." (Docket 349 at 8) This is a distinction without a difference and, moreover, *Baze* never draws it.

It is elementary that a plaintiff must plead the "core elements" of the relevant cause of action: "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). If liability for an Eighth Amendment violation requires proof that defendant has, but refuses to use, "a feasible and more humane alternative method of execution," then that "core element" must be pleaded to properly aver "that the defendant is liable for the misconduct alleged." The difference defendants try to draw here – between a "heightened pleading requirement" (not required under *Hill* and *Jones*) and pleading a "core element" (supposedly required under *Baze*) – is illusory.

Moreoever, *Baze* draws no such distinction. Nowhere in the *Baze* plurality, or in any of the concurrences, does any of the Justices even mention *Hill* or *Jones*, let alone say they are overruling those decisions or distinguishing them for concerning a "heightened pleading requirement" rather than a "core element" of an Eighth Amendment claim. Defendants' argument is simply made up and, in any event, totally unsupported.

In the same vein, defendants claim that, because two Justices in *Baze* would have required Eighth Amendment plaintiffs to show an execution protocol involves the "intentional infliction of gratuitous pain," 553 U.S. at 102 (Thomas, J., concurring), the three-Justice plurality is really a five-Justice majority opinion that, *sub silentio*, overruled *Hill* and *Jones*. (Docket 349 at 7)

Besides ignoring the fact that *sub silentio* overrulings are not the practice of the Supreme Court, defendants forget to inform this Court that Justice Thomas, in writing the two-Justice opinion they invoke, explained: "I write separately because I cannot subscribe to the plurality opinion's formulation of the governing standard." 553 U.S. at 94 (Thomas, J., concurring). Indeed: "I reject as both unprecedented and unworkable any standard that would require the courts to weigh the relative advantages and disadvantages of different methods of execution or of different procedures for implementing a given method of execution." *Id.* at 106. As such, the two-Justice opinion defendants invoke expressly *rejects* the notion that Eighth Amendment plaintiffs are required to plead an alternative and lawful method of execution.

Defendants are left, then, with the three-Justice plurality. As discussed in Taylor's motion and not disputed by defendants, the three-Justice plurality cannot overrule unanimous prior decisions of the Court. Moreover, it is unreasonable to think that two of those three Justices – Chief Justice Roberts and Justice Kennedy – understood the plurality opinion to overrule unanimous opinions – *Jones* and *Hill*, respectively – that each of them had recently authored. Also undisputed is that, given the doctrine of *stare decisis*, the Court is not likely to overrule *Hill* and *Jones*, which "unanimously reject[] a proposal that § 1983 suits challenging a method of execution must identify an acceptable alternative." *Jones*, 549 U.S. at 213. The ruling ripe for reversal is the Eighth Circuit's claim to the contrary.

In sum, it is significantly possible the Supreme Court will reverse the Eighth Circuit, which claimed to create a new rule for Eighth Amendment cases that is squarely foreclosed by unanimous Supreme Court precedents.

C. Irreparable Harm

Defendants do not dispute – nor could they persuasively – that Taylor faces irreparable harm absent a stay and that such harm outweighs the state's desire to execute him before the Supreme Court rules.

To summarize, the legal standard for Taylor's motion to stay his execution pending certiorari is set out in *Barefoot*. Defendants ignore that standard and, as discussed in Taylor's motion and above, he meets it. The Court should therefore stay Taylor's execution for the relatively short time it will take the Supreme Court to either grant or deny certiorari.

II. If the Merits of the Underlying Litigation are Relevant here, They Also Favor a Stay Pending Certiorari

A stay pending certiorari is warranted under the *Barefoot* standard. A stay is likewise warranted if the Court expands the inquiry to include the merits of the underlying litigation. Defendants dispute nothing Taylor has said as to that:

- The press has now reported the identity of the pharmacy that provides Missouri with the execution drugs. Two days ago, plaintiffs renewed their previously un-actionable complaint before the Missouri Board of Pharmacy. (Exhibit B) Claims similar to those raised to the Board of Pharmacy are alleged in plaintiffs' complaint here. (Docket 338 at Claims IV, IX)
- The due-process and equal-protection violations plaintiffs allege (Docket 338 at Claim VIII) are no longer a matter of speculation. Judge Laughrey ruled that, although defendants violated their own protocol by executing Mr. Franklin while he had legal appeals pending, there was no indication defendants would "do it again." (Docket 196 at 10) Yet they now have, executing all three former plaintiffs Franklin, Nicklasson, Smulls while all three had applications pending in court. (Docket 343 at Ex. C) Missouri's practice is, as far as plaintiffs can tell, unique in the United States.

- Taylor's opportunity to analyze the "physical evidence relating to Smulls' execution, including any leftover pentobarbital, used and unused syringes, medical tubing, and any other materials that would otherwise be disposed" (Docket 322), may provide evidence the Court previously found lacking. He should have an opportunity to analyze these items before the state is allowed to execute him.
- Plaintiffs' Second Amended Complaint pleads new facts and causes of action that provide additional grounds to rule for plaintiffs.
- The Supreme Court is currently weighing the certiorari petition in *Sepulvado v. Jindal*, Sup. Ct. No. 13-892, which poses a due-process question comparable to plaintiffs' (Docket 338 at Claims VII and VIII) given that "Missouri has changed the [execution] protocol numerous times since May 2012, while still actively scheduling new executions." (Docket 343 Ex. A at 12) Sepulvado recently received a 90-day stay from a lower court; Taylor merits the same for the briefer time it will take the Supreme Court to grant or deny certiorari.

In sum, facts change and new information emerges on a regular basis in this case. The developments above came after one or all of the executions in the past three months and, since all three of those executions, the Supreme Court issued the CFR signaling it is seriously considering plaintiffs' certiorari petition. Defendants are thus again mistaken in claiming "[n]othing has changed in two weeks."

(Docket 349 at 4) Just yesterday, in fact, the Missouri House Committee on Government Oversight and Accountability held a hearing on defendants' protocol at which the lead defendant, Mr. Lombardi, "bemoaned all of the attention surrounding the department over the state's execution procedures." (Exhibit C)

Public attention regarding a state's execution procedures is vital, however, to ensuring that the state acts lawfully when it inflicts the ultimate punishment. As Judges Bye and Kelly have noted, Missouri has resisted public oversight by "using shadow pharmacies hidden behind the hangman's hood" and making "numerous

last-minute changes to its execution protocol" (Docket 343 at Ex. A at 15), but there have been significant moves recently to end such secrecy and enable meaningful review of both the protocol and plaintiffs' claims.

One of those claims is now before the Supreme Court, which has indicated it is seriously considering taking the case. This Court may grant Taylor a stay pending certiorari, and it should do so because he meets the standard for one. Taylor has shown a reasonable probability of certiorari, a significant possibility of reversal, and that the irremediable harm he faces absent a stay outweighs the state's desire to execute him before the Supreme Court rules.

CONCLUSION

The Court should stay Taylor's execution pending the Supreme Court ruling on plaintiffs' pending certiorari petition.

Respectfully submitted,

SEAN K. KENNEDY Federal Public Defender

DATED: February 11, 2014 By <u>s/Matthew B. Larsen</u>

MATTHEW B. LARSEN Deputy Federal Public Defender

EXHIBIT A

IN THE SUPREME COURT OF THE UNITED STATES

DAVID ZINK, et al.,)	
Petitioners,)	
v.)	Nos. 13-8435, 13A784
GEORGE LOMBARDI, et al.,)	
Respondents.)	

SUGGESTIONS IN OPPOSITION TO MOTION FOR STAY OF EXECUTION AND TO PETITION FOR WRIT OF CERTIORARI

I. This Court should not grant a stay of execution.

Smulls asks this Court to enter a stay of execution because he disagrees with a decision of the United States Court of Appeals for the Eighth Circuit en banc on a discovery dispute. The thrust of the ruling is that Smulls and his co-plaintiffs are not entitled to certain discovery because their complaint was defective in that it did not allege there was any feasible, more humane alternative method of execution.

Smulls fails to mention that the district court denied Smulls's application for stay of execution because the district court found that even if Smulls had properly pled his claim he would not be entitled to a stay in that he cannot show a significant likelihood of success on the merits. Zink v. Lombardi, No. 12-4209, Document 308 at 5. Smulls does not include this document in his appendix. Smulls's argument to this Court ignores the

reality that the denial of his stay application was independent of the ruling he complains about. It also ignores that two of his co-plaintiffs, Franklin and Nicklasson, were denied stays based on the same underlying lawsuit before the court of appeals made the ruling Smulls complains about. Zink v. Lombardi, No. 12-4209, Document 308 at 2-3. Smulls is not entitled to a stay of execution regardless of whether the certiorari petition should receive further consideration. But this Court should not grant certiorari.

II. This Court should not grant the petition for a writ of certiorari.

Smulls alleges that the decision of the Court below interprets this Court's precedent in a manner supported by the United States Court of Appeals for the Fifth and Sixth Circuits, but allegedly in conflict with two decisions of the United States Court of Appeals for the Ninth Circuit (Certiorari Petition at 13). But there is no real conflict with the Ninth Circuit cases Smulls cites. Cook v. Brewer, 637 F.3d 1002 (9th Cir 2011) and Cook v. Brewer, 649 F.3d 915 (9th Cir. 2011) were both cases in which the United States Court of Appeals for the Ninth Circuit affirmed the dismissal of complaints about lethal injection for failure to state a claim on which relief can be granted, not cases in which the court of appeals found the plaintiffs stated a claim despite not alleging a more humane method of execution was available.

The remainder of the petition is a very fact-specific argument that the decision of the court of appeals on the discovery issue is moot, and a complaint about the court of appeals's use of its supervisory authority. (Certiorari Petition at 14-20). Neither issue is appropriate for certiorari review by this Court.

Respectfully submitted,

CHRIS KOSTER

Attorney General

/s/ Michael J. Spillane

MICHAEL J. SPILLANE Assistant Attorney General Counsel of Record Missouri Bar No. 40704 PO Box 899 Jefferson City MO 65102 Phone: 573.751.0967

Fax: 573.751.3825

mike.spillane@ago.mo.gov

ATTORNEYS FOR PETITIONERS

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was electronically filed by using the CM/ECF system on this 28th day of January 2014. This Court's electronic filing system should serve counsel for the plaintiffs, as all are electronic filers, and a copy was emailed to:

Elizabeth Carlyle-Unger elizabeth@carlyl-law.com

John Simon simonjw1@yahoo.com

Joseph Luby jluby@dplclinic.com

/s/ Michael J. Spillane

MICHAEL J. SPILLANE Assistant Attorney General

EXHIBIT B

DEATH PENALTY LITIGATION CLINIC

6155 Oak Street, Suite C Kansas City, MO 64113

(816) 363-2795 (816) 363-2799 Fax dplc@dplclinic.com http://www.dplclinic.com

Attorneys

Rebecca E. Woodman, Executive Director Joseph W. Luby Jessica E. Sutton Sonali Shahi

February 9, 2014

Via Fax to 573-526-3464, U.S. Mail, and email to MissouriBOP@pr.mo.gov

IMMEDIATE ACTION REQUESTED

Kimberly Grinston, Executive Director Missouri Board of Pharmacy 3605 Missouri Boulevard P.O. Box 625 Jefferson City, MO 65102

Re: Complaint No. 2013-006647

Dear Ms. Grinston:

Your letter of January 22, 2014, states the Board voted to take no action on my complaint involving the Missouri Department of Corrections' receipt of execution drugs. The Board relied on two reasons: first, the identity of the offending pharmacy is unknown, and second, that the Board does not have jurisdiction "over entities that obtain prescription medication," i.e., the Department of Corrections. I am writing today because intervening events undermine both reasons for the Board's inaction, and indeed, require <u>immediate</u> action to prevent and remedy violations of the Board's regulations and other binding law.

First, The Apothecary Shoppe of Tulsa, Oklahoma, has been revealed as the Department of Corrections' supplier of compounded pentobarbital, based on publicly available documents revealed by the Department of Corrections itself. I have enclosed articles from the Kansas City Star, St. Louis Public Radio, and the Pitch Weekly, all reporting this fact, which I am reporting to you under the protections of

Mo. Rev. Stat. § 338.155.1.

Second, The Apothecary Shoppe received a Missouri pharmacy license on Monday, February 3, 2014, with the name "David K. Johnson" designated as the "Pharmacist in Charge." The Apothecary Shoppe holds Licensee Number 2014003447. Because the Apothecary Shoppe holds a Missouri pharmacy license, there is no question that the Board of Pharmacy has jurisdiction over its licensee's conduct.

The Board is already familiar with the substance of The Apothecary Shoppe's violations, based on the complaint that I filed as well as two letters I later sent the Board. Copies of all of these documents are enclosed. Nevertheless, it bears repeating that The Apothecary Shoppe's activities are in <u>clear and unambiguous</u> violation of the law:

- •Copying an FDA-approved drug The Apothecary Shoppe makes compounded pentobarbital as a copy of FDA-approved pentobarbital that is sold and marketed as Nembutal. The Board's regulations expressly prohibit the "compounding of drug products ... that are essentially copies of commercially available Federal Drug Administration (FDA) approved drug products." 20 Mo. C.S.R. § 2220-2.400(9).
- Dispensing the drug without a valid prescription The Apothecary Shoppe hands over its product to the Department of Corrections for "subsequent ... administration," but without the bona fide doctor-patient relationship required by law, i.e., "in the course of professional practice for a prescriber to administer to an individual patient by prescription." 20 Mo. C.S.R. § 2220-2.400(12). Far from relying on a legitimate prescription offered in the course of medical practice, The Apothecary Shoppe dispenses its product based on the prescription of a physician who issues it on demand of the Department of Corrections; the prescribing physician has no medical relationship with the prisoner and does not even examine the prisoner or his medical records. I have enclosed a copy of the prescriber's contract with the Department of Corrections, which shows that a prescription issues only because the Department demands it.
- <u>Violations of federal drug laws</u> The Board requires its licensees to obey all applicable state and federal laws. *See* 20 Mo. C.S.R. § 2220-2.013(4) ("Licensees shall comply with all applicable controlled substance laws and regulations[.]"); 20 Mo. C.S.R. § 2220-2.018(1)(K) ("Controlled substance prescriptions shall also comply with all requirements of federal and state controlled substance laws."). Yet, The Apothecary Shoppe is multiple committing federal felonies. By dispensing a controlled substance without a valid prescription issued in the usual course of medical

practice, The Apothecary Shoppe is violating the Controlled Substances Act, and its pharmacists are subject to federal imprisonment for up to ten years. See 21 U.S.C. § 841(a)(1), 841(b)(1)(E)(I); 21 C.F.R. § 1306.04(a) ("An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.") (emphases added). Second, The Apothecary Shoppe's compounded drug is an "unapproved new drug" under the Food, Drug, and Cosmetic Act—as recently amended by the Drug Quality and Security Act—because, once again, it is an illegal "copy" of an FDA-approved drug. See Pub. L. No. 113-54, 127 Stat. 587 (Nov. 27, 2013), § 102(a) (modifying scope of FDCA § 505). To dispense an unapproved new drug, or to distribute it within interstate commerce, is a federal crime punishable by up to one year of imprisonment. See 21 U.S.C. §§ 331 (a), (d).

RELIEF REQUESTED - The Board must take <u>immediate</u> action to restrain The Apothecary Shoppe from violating state and federal law. This matter is extremely urgent, because prisoner Michael Anthony Taylor is scheduled for execution on February 27. The Apothecary Shoppe's contract with the Department of Corrections requires it to compound and furnish the pentobarbital no later than fifteen days before the scheduled execution. This deadline is fast-approaching, and it is essential that you (a) issue a cease and desist order directing The Apothecary Shoppe not to compound or dispense pentobarbital, (b) seize the offending compounded pentobarbital if it has already been manufactured, (c) seek appropriate judicial and administrative enforcement of the Board's lawful and binding regulations.

Thank you for your prompt attention to this matter.

Sincerely yours,

oseph W. Luby

CC: Chief Inspector Tom Glenski, R.Ph., via email to tom.glenski@pr.mo.gov

EXHIBIT C

- **My Profile**





Missouri corrections officials defend executions



The state, once among the nation's more active death penalty states, resumed carrying out executions for the first time in nearly three years as the Department of Corrections adopted a new method for killing inmates—a single dose of the pow erful sedative pentobarbital. The drug was used in November to execute serial killer Joseph Franklin, who was convicted of a 1977 sniper shooting at a suburban St. Louis synagogue. It was used again in December to execute Allen Nicklasson, convicted in the killing of a Good Samaritan in 1994.

by Associated Press

KMOV.com

Posted on February 11, 2014 at 3:34 AM

Updated today at 7:07 AM

JEFFERSON CITY, Mo. (AP) -- Missouri's top corrections official defended the state's current execution procedures while telling lawmakers Monday the state could not carry out lethal injections if the name of the company that provides the execution drug

Case 2:12-cv-04209-BP Document 350 Filed 02/11/14 Page 22 of 25 http://www.kmov.com/news/mobile/Mo-corrections-officials-defend-executions-244838221.html

wasn't kept secret.

Corrections Department Director George Lombardi told a House panel that it was vital to protect the identity of all those involved in executions, including the drug supplier.

"They made it very clear to us that we would not have people to carry out the mandated statutory requirement of the death penalty. They just wouldn't do it," Lombardi said.

Missouri and other states for decades had used a three-drug execution method, but pharmaceutical companies stopped selling the drugs in recent years for use in executions. Missouri eventually switched to pentobarbital, a powerful sedative acquired from a compounding pharmacy, which was used to execute serial killer Joseph Paul Franklin and Allen Nicklasson last year, and Herbert Smulls on Jan. 29.

The state considers the pharmacy to be a member of the "execution team," which protects its identity from public records requests filed under state law.

Lombardi said the state pays \$8,000 in cash to the pharmacy for the drug. The department then pays for the batch to be independently tested to make sure it works and is sterile. He added that the department found no substantial issues in a background check of its current supplier.

Kansas City attorney Joseph Luby, who represents death row inmates, told the House Government Oversight and Accountability Committee that the protocol prevents defendants from getting information that would be critical in appealing their sentences. He said the department's decision to not reveal the compounding pharmacy's identity was "sleazy."

"The department's methods, contracts and practices have been shrouded in secrecy in a way that prevents meaningful public scrutiny," he said.

Luby also raised concerns that the last three lethal injections in Missouri had been conducted while the inmate's attorneys were in the process of asking a federal court for a stay.

That argument was countered by Dave Hansen of the attorney general's office, who said pending litigation is not a reason to delay or stop an execution.

"The offender's attorneys have developed a legitimate and very deliberate strategy to ensure there is always a stay motion pending during the course of a death warrant, which is a de facto repeal of the death penalty," he said.

Committee Chairman Rep. Jay Barnes, R-Jefferson City, said Monday's hearing was

not about the death penalty itself, but making sure the current method was carried out according to the Constitution.

But other state lawmakers are citing legal issues with the current method to propose changing the state's procedure. Bills have been introduced to halt executions until a special commission can develop new guidelines subject to legislative oversight. Other proposals would simply repeal the death penalty.

Lombardi bemoaned all of the attention surrounding the department over the state's execution procedures and said people should focus on the department's record when it comes to prisoner re-entry.

"This whole issue and the way our department has been be mirched and vilified in the press especially is really disturbing to me, because this is not what this department is about," Lombardi said.

Missouri's next scheduled execution is that of Michael Taylor on Feb. 26. Taylor pleaded guilty in the 1989 abduction, rape and stabbing death of a 15-year-old Kansas City girl.

CERTIFICATE OF SERVICE

I hereby certify that on February 11, 2014, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notification of such filing to counsel for defendants, who are registered CM/ECF users here.

s/Matthew B. Larsen
MATTHEW B. LARSEN